



Does the presence of sensory hypersensitivity influence outcomes of physical rehabilitation for chronic whiplash? – A preliminary RCT

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Abstract

Patients with chronic whiplash associated disorders present with varied sensory, motor and psychological features. In this first instance it was questioned whether a multimodal program of physical therapies was an appropriate management to be broadly prescribed for these patients when it was known that some would have sensory features suggestive of a notable pain syndrome. A randomised controlled trial was conducted with 71 participants with persistent neck pain following a motor vehicle crash to explore this question. Participants were randomly allocated to receive either a multimodal physiotherapy program (MPT) or a self-management program (SMP) (advice and exercise). In the randomisation process, participants were stratified according to the presence or not of widespread mechanical or cold hyperalgesia. The intervention period was 10 weeks and outcomes were assessed immediately following treatment. Even with the presence of sensory hypersensitivity in 72.5% of subjects, both groups reported some relief of neck pain and disability (Neck Disability Index) and it was superior in the group receiving multimodal physiotherapy ($p = 0.04$). Post-hoc observations however suggested that relief was marginal in the subgroup with both widespread mechanical and cold hyperalgesia. Further research is required to test the validity of this sub-group observation and to test the effect of the intervention in the long term.

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1. Introduction

Management of patients with chronic whiplash associated disorders (WAD) remains a challenge. While many individuals recover within a few weeks of injury, a significant proportion (14–42%) has persistent ongoing pain with 10% reporting constant severe pain (Barnsley et al., 1994). Berglund et al. (2000) estimated that there was a relative risk of 2.7 (95% CI 2.1, 3.5) of developing chronic neck pain if acute neck pain began soon after

the motor vehicle crash. It is those with persistent symptoms who contribute substantially to the significant economic and personal costs related to this condition internationally.

Currently, many patients seek ongoing physical therapies from a variety of practitioners for their persistent neck pain, months after their injury. Decisions as to who should receive physical therapies at this stage appear to be largely indiscriminate (Flanaghan and Green, 2000; Flanaghan et al., 2003). This situation is concerning for patients, health professionals and insurers alike, but is understandable as to date, only one clinical trial has been found which has investigated the effects of physical therapies such as exercise specifically for this

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group with chronic whiplash associated disorders (Fitz-Ritson, 1995). Clearly more clinical trials are needed.

From our experience with chronic WAD, it appears that physical therapies may assist some patients but may aggravate symptoms in others, suggesting that persons with chronic whiplash associated disorders are a heterogeneous group. This was confirmed in our recent prospective study of acute whiplash injury which monitored sensory, motor and psychological features over a six-month period (Sterling et al., 2003a,b,c). Persistent symptoms at 6 months were associated with varying degrees of physical and psychological disturbances. A notable finding was the widespread hypersensitivity (lowered pain thresholds) to thermal and mechanical stimuli and diminished sympathetic vasoconstriction that were variously present particularly in those reporting ongoing moderate to severe pain and disability (Sterling et al., 2005). Similar disturbances have also been documented by other researchers (Koelbaek-Johansen et al., 1999; Curatolo et al., 2001) and likely indicate the presence of augmented central pain processing mechanisms in some patients.

There are many factors which could confound the design of a clinical trial for the management of patients with chronic WAD considering their potential heterogeneity in presentation. In this first instance, we questioned whether physical therapies were an appropriate management to be broadly prescribed for these patients when many were likely to have abnormal sensory responses. To investigate this question, we conducted a preliminary randomised controlled trial for chronic whiplash patients classifiable as WAD II (Spitzer et al., 1995). The immediate effectiveness of a multimodal physical therapy program (MPT) was tested against a self-management program (SMP). We hypothesised that MPT would be more effective than a SMP in reducing the reported pain and neck disability of patients with chronic WAD II. To account for differences in presentation in relation to sensory features, participants were stratified according to abnormal values in pressure pain and cold pain thresholds prior to randomisation into the MPT or SMP groups.

2. Methods

2.1. Study design

The study was a prospective randomised controlled trial (RCT) to test the effectiveness of MPT for subjects with chronic whiplash disorders, classified as WAD II against a SMP consisting of information about whiplash, advice to stay active and exercise. The design with a comparison SMP was used as many subjects were still likely to be involved in compensation claims and self-management with an emphasis to stay active is a legitimate management approach. The trial was a single blind trial design with blinded outcome assessment. The nature

of the interventions (MPT delivered by physiotherapists versus self-management) precluded blinding of treaters and subjects. A dynamically randomised design was used to ensure good balance of treatment allocation across three stratification factors suggestive of the presence of abnormal pain processing in the WAD II syndrome. The treatment period was of 10 weeks duration, MPT being a minimum of 10 treatments and a maximum of 15 treatments, which respected the chronicity of the disorder and time needed to ensure adequate rehabilitation. The RCT tested only the immediate effects of treatment after the 10 week intervention period in this first instance. This design feature was chosen to answer our primary question of whether physical therapies can be widely prescribed for cases of chronic whiplash. This knowledge is required either before an efficacious treatment can be ethically withheld to allow for a long-term 12 month follow-up of subjects involved in compensation, or conversely if this type of treatment should not be generally offered to patients with chronic WAD.

2.2. Subjects

Volunteer participants of both genders and aged between 18 and 65 years were sought for the study through referral from general practitioners or through general advertising in the popular press. They were considered for the study if they were suffering from persistent neck pain and disability (between 3 months and 2 years post-injury) resulting from a motor vehicle crash, were classifiable as WAD II (Spitzer et al., 1995) and were willing to undertake either the MPT or the SMP for a period of 10 weeks. We accepted the subjects' reports that the onset of their neck condition was associated with motor vehicle crash. As there were no financial gains for subjects who volunteered for the RCT, we have no basis to suspect that any subject mislead us on this association. Volunteers were not considered if their condition was classifiable as WAD III or IV, they had had neck pain from a previous neck condition or motor vehicle crash, were not fluent in spoken and written English to be able to complete questionnaires independently or were currently receiving physical therapy treatments.

Seventy-one participants entered the study. The sample size calculation was based on an 8% change in the Northwich Park Neck Pain Index, which has been determined to be a clinically relevant change (Leak et al., 1994). Forty-four patients (22 per group) were required to detect a difference between the MPT and SMP groups, with a standard deviation of 8, at 90% power, and 95% confidence. However, it was believed up-front that a proportion of patients would not benefit from treatment. On the basis that abnormal sensory features are present in 55% of a preselected chronic group of WAD subjects (Sterling et al., 2000) and also present in 36% of a sub-acute group tracked over time (Sterling et al., 2003a), we assumed that up to 45% of patients would fit into this category. The sample size would need to be 1.45 times as large to allow for this (64 patients). We expected the drop out rate to be low in this contained RCT, but taking the case that there would be a drop out rate of 10%, the sample was increased to 70 subjects (35 per group). Ethical clearance was gained from the Institutional Medical Ethics Committee and all procedures were conducted according to the Declaration of Helsinki. Subjects provided written informed consent prior to participation.

2.3. Measurements

A questionnaire was designed to gain baseline data on subject demographics, accident history, current symptoms and compensation status. The primary outcome measure was the change from baseline in Northwich Park Neck Pain Index (NPI) (Leak et al., 1994), a validated questionnaire, which measures patient's self-rated neck pain and disability. Several secondary outcome measures were undertaken inclusive of measures of both physical and psychological impairment. These included range of cervical motion measured with a 3D external measurement device (Fastrac) (Dall'Alba et al., 2001) and a cervical muscle test, the cranio-cervical flexion test (Jull, 2000). The cranio-cervical flexion test was chosen as the measure of muscle function in this study as impairment in the neck flexor synergy has been measured with this test in subjects with neck pain of both idiopathic and whiplash origin (Jull, 2000; Falla et al., 2004; Jull et al., 2004a; Chiu et al., 2005). In addition, an exercise program which has a focus on re-educating these muscles has been shown to be effective for the relief of neck pain (Jull et al., 2002). This test measures the activity (electromyography) of the deep and superficial flexor muscles in a five-staged task of cranio-cervical flexion, the anatomical action of the deeply placed longus capitis and longus colli muscles (Falla et al., 2004). The deep cervical flexors are accessed by a bipolar surface electrode inbuilt into a nasopharyngeal catheter that is inserted via the nasal cavity and suctioned onto the oropharynx over the longus capitis and coli (Falla et al., 2003). Neck pain patients exhibit an altered pattern of muscle activity with less measured activity in the deep muscles associated with higher measured activity in the superficial flexors compared to asymptomatic subjects (Falla et al., 2004). In this study, the clinical version of the test was used which measures activity in the superficial flexors only, following methodology previously described (Jull, 2000; Jull et al., 2004a). Three psychological tests relevant to chronic whiplash were chosen and included the General Health Questionnaire 28 (GHQ-28), a 28-item measure of emotional distress (Goldberg, 1978); the TAMPA Scale of Kinesophobia (TSK) (Kori et al., 1990), a 17-item questionnaire that measures the fear of re-injury due to movement and the Impact of Events Scale (IES), a 15-item questionnaire that measures current participative stress related to a specific life event (Horowitz et al., 1979). Subjects' perceptions of treatment efficiency and the relief gained were assessed using two 10cm VAS scales. The subject was provided with two statements. The first was "The treatment benefited me" and the VAS was anchored with the descriptions 'Not at all' and 'The most I can imagine'. The second statement was "I have gained relief of my neck disorder" and the anchors were 'Not at all' and 'Completely'.

2.4. Stratification and randomisation procedure

Subjects were stratified according to psychophysical measures suggesting the presence of altered pain processing. For the purposes of this study, these were pressure pain thresholds (PPT) over the median nerve trunk in the upper limb and from a remote site over the tibialis anterior muscle, measured using a pressure algometer (SomedicAB, Sweden) (Sterling et al., 2000, 2002). Cold pain thresholds (CPT) were measured over the cervical region using a ThermoTest System (Somedic AB,

Sweden). To determine if these variables could separate WAD subjects, we performed a Quick Cluster Analyses of PPT data obtained in our laboratory from 110 chronic WAD patients with persistent symptoms who were not responding to treatment. We also analysed PPT and CPT data of 33 sub-acute WAD patients, 3 months post-whiplash (Sterling et al., 2003a). Subjects could be clustered into three groups on the basis of PPTs. Of the 110 chronic WAD subjects, compared to normative data (Sterling et al., 2000), 55% had clearly abnormal PPTs, and the remainder were within the normal range, albeit skewed to lower values. Of the 33 subacute WAD subjects, 36% had clearly abnormal PPTs and CPTs. The stratification for randomisation was based on these analyses and three factors were used. PPT values over the tibialis anterior were regarded as the primary factor (F_1), CPTs over the cervical region as the second factor (F_2), and PPTs over the median nerve trunk as the third strata (F_3). The values for abnormal responses represent those outside the values for normative data. Table 1 presents the values by which subjects were stratified prior to randomisation. Dynamically balanced randomisation was used to allocate the next treatment that would best balance the allocation over all the stratification factors. This meant that any post-hoc observations using these factors would be well balanced for treatment allocation. The Queensland Clinical Trials Centre provided the randomisation service. A research assistant used a computerised randomisation algorithm to allocate the next treatment, on receipt of a telephone call confirming the subject's eligibility for the trial and provision of stratification factor information.

2.5. Interventions

The MPT was a multimodal physical therapy program that was purposefully low load in nature to avoid provocation of symptoms in this pain group of chronic whiplash. The program has proven effective for patients with idiopathic neck pain (Jull et al., 2002) and it is described in full elsewhere (Jull et al., 2004b). It included specific low load exercises aimed to re-educate muscle control of the neck flexor and extensor muscles and those of the scapular region as well as their incorporation into posture and functional activities. Subjects also undertook exercises aimed to retrain kinaesthetic sense (Revel et al., 1994) as such deficits are common in chronic WAD (Treleaven et al., 2003). The manipulative therapy included only low velocity mobilising techniques (Maitland et al., 2005). Education and assurance was provided including ergonomic advice on activities of daily living, correct work practices and work environment. Subjects were encouraged to continue exercises at home and completed an exercise compliance diary.

Table 1
Values for factors in the stratification process

Factor	Test	Value	
		Males	Females
F_0	PPT tibialis anterior	>410 kpa	>304 kpa
F_1	PPT tibialis anterior	<410 kpa	<304 kpa
F_2	CPT cervical region	>14.4°	>14.6°
F_3	PPT median nerve	<285 kpa	<200 kpa

PPT, pressure pain threshold; CPT, cold pain threshold; and kpa, kilopascals.

The SMP was documented in a booklet that was provided to each subject. It included education about the mechanism of whiplash, assurance on recovery and stressed the need to stay active. The ergonomic advice on activities of daily living, correct work practices and work environment was similar to that provided to the MPT group as was the description of the exercise program. Subjects were encouraged to perform the exercise program at least twice per day and completed an exercise compliance diary.

2.6. Data management and analysis

Change scores were analysed and analysis was conducted on an intention to treat principle and between group differences were analysed using a repeated measures linear regression. The effect size for the primary outcome (NPI) was calculated by taking the difference between the mean changes of the MPT and SMP and dividing it by the standard deviation of the change score of the total population. An effect size of 0.2 was regarded as small, 0.5 as medium, and 0.8 as large (Cohen, 1977).

3. Results

Participant flow and retention are presented in Fig. 1 and baseline characteristics of the MPT and SMP groups in Table 2. There were no significant differences in baseline variables between the groups (all $p > 0.05$). Subjects reported moderate levels of pain and disability (NPI) elevated levels of psychological distress (GHQ 28), fear of re-injury due to movement (TSK) and post-traumatic stress (IES).

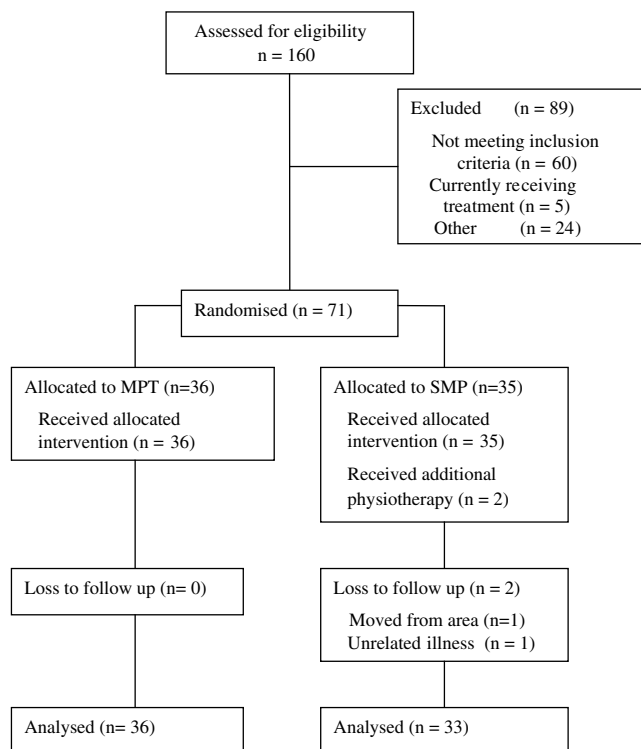


Fig. 1. Participant flow and retention.

Table 2
Baseline demographics of the multimodal physical therapy (MPT) and self-management (SMP) groups

	MPT (n = 36)	SMP (n = 35)
Age (years)	40.9 ± 11.9	38.4 ± 10.4
Gender (% female)	62.8	80.6
Time since injury (months)	13.3 ± 6.0	12.0 ± 7.4
NPI (score %)	37.7 ± 13.8	38.4 ± 11.2
Compensation status (%)		
Current	67.5	80.0
Settled	17.1	5.7
No claim	17.1	14.3
GHQ 28	31.5 ± 14.3	31.7 ± 11.3
TSK	41.9 ± 5.3	43.5 ± 6.1
IES	21.5 ± 15.1	21.2 ± 15.4

The mean changes in the primary and secondary outcomes are presented in Table 3 and the outcome of the cranio-cervical flexion test is presented in Fig. 2. Both groups achieved some benefit from the interventions, but after adjusting for baseline scores, the analysis revealed that the MPT group attained a significantly greater reduction in reported neck pain and disability (NPI) than the SMP group ($p = 0.04$). The effect size of this primary outcome was calculated as 0.48. This difference was also reflected in scores on the VAS of patients' perceived benefits of treatment (MPT 7.3 ± 1.9; SMP 4.2 ± 2.7) and perceived relief of symptoms (MPT 6.9 ± 1.9; SMP 4.2 ± 2.7). There was no difference in range of movement gain between the MPT and SMP groups (all $p > 0.35$) and range improved similarly by approximately 10 degrees in each plane. Data from the cranio-cervical flexion test were initially analysed for any between side differences in nRMS amplitudes for each stage of the test (Bland Altman Limits of Agreement). No between side differences were determined and in consequence the mean of both sides was used for analysis. Regression analysis revealed significant differences between the MPT and SMP groups in results of the cranio-cervical flexion test ($p < 0.018$). There was greater improvement in the muscle function

Table 3
The change in the primary and secondary outcome of the multimodal physical therapy (MPT) and self-management (SMP) groups

Outcomes	MPT	SMP
<i>Primary</i>		
NPI (%)	-10.4 ± 14	-4.6 ± 8.8
<i>Secondary</i>		
ROM (°)		
Flex/ext	+9.6 ± 13.2	+8.5 ± 13.2
Rotation	+14.1 ± 11.9	+9.5 ± 9.0
Lateral flexion	+10.2 ± 7.1	+10.6 ± 6.7
GHQ 28	-5.5 ± 6.3	-2.7 ± 8.1
TSK	-1.3 ± 4.3	-3.4 ± 4.3
IES	-4.8 ± 11.6	-1.5 ± 15.1

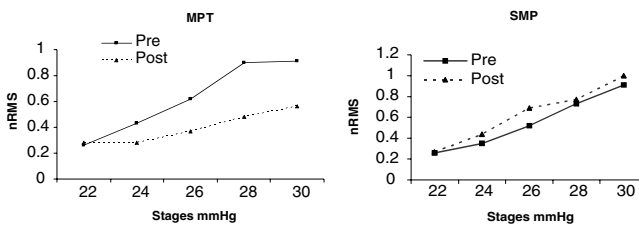


Fig. 2. The mean normalised root mean square nRMS EMG values for the sternocleidomastoid muscles pre and post-intervention periods for the multimodal physical therapy (MPT) and self-management (SMP) groups.

test of cranio-cervical flexion in the MPT group with significant negative changes in nRMS signal amplitudes of the superficial neck flexors in performance of the test post-intervention at the 24 mm Hg ($p = 0.016$), 26 mm Hg ($p = 0.018$), 28 mm Hg ($p = 0.02$) and 30 mm Hg ($p = 0.03$) stages of the test (Fig. 2). No significant pre- to post-intervention change was observed within stages when subjects performed the exercise program in a self-administered manner (SMP). Changes were present but marginal in the psychological features (Table 3). There were no between group differences in change scores in GHQ 28 ($p = 0.28$) although psychological distress approached threshold values (23/24) in the MPT group. Likewise there were no differences between the groups for changes in IES scores ($p = 0.15$) although there were differences in TSK scores where the changes were significantly greater in the SMP group ($p = 0.02$).

Post-hoc, the subjects within groups were separated on the basis of the presence or not of one or more sensory features. They were grouped as presenting with: no abnormal sensory features, widespread mechanical hyperalgesia (decreased PPTs in the upper and lower limbs), both widespread mechanical and cold hyperalgesia (decreased PPT + elevated CPT) and cold hyperalgesia only (elevated CPT). The distribution of subjects within these categories, baseline NPI scores and change scores following the intervention are presented in Table 4. Of interest, 72.5% of all chronic WAD subjects in this study presented with some sensory abnormality and those presenting with features of either widespread mechanical hyperalgesia or both mechanical and cold hyperalgesia presented with higher baseline scores on

the NPI. Considering the baseline NPI scores, it appears that the treatment effect of MPT might be less for the group presenting with both mechanical and cold hyperalgesia, with a comparable improvement noted in the SMP group.

4. Discussion

The results of this preliminary clinical trial indicate that a multimodal physical therapy program (MPT) can gain an immediate reduction in self-reports of pain and disability in patients with chronic whiplash associated disorders, even though there was heterogeneity in their presentation in relation to sensory hypersensitivity. While both groups showed some improvement, the change in NPI scores in the MPT group was significantly greater than that achieved with a self-management program (SMP). The effect size was moderate (0.48) in this challenging group and sufficient to suggest that physical therapies are warranted in management of patients with chronic WAD. The subjects perceived that they had gained benefit from MPT and reported a mean 70% relief of symptoms, despite reporting only a mean 10.4% change in the NPI score. This probably reflects the moderate correlation only between the change in the NPI and patient's overall assessment of change in neck pain and handicap previously reported for this questionnaire (Wlodyka-Demaille et al., 2004). Improvements occurred in range of cervical motion in both groups, but improvement in the pattern of muscle control as measured in the CCFT was only evident in the MPT group, suggesting that when specific muscle re-education is indicated, patients require guidance in the re-education exercises from a skilled practitioner if an effective change in performance is to be achieved.

The unblinded nature of treatments and the knowledge of subjects in the SMP group, that they were members of the comparison treatment group, might be perceived as a factor influencing outcomes. This is especially so in this field of whiplash where, as seen in this study, psychological features play a part in the disorder. However, we would argue that the presence of a physiotherapist in the MPT intervention was unlikely to be the major factor contributing to the outcomes, as observed in outcomes pertaining to psychological features.

Table 4

The division within the MPT and SMP groups based on the presence or not of abnormal sensory features, baseline scores and change scores in the Neck Pain Index following the intervention

	Sensory response	MPT			SMP		
		<i>n</i>	NPI Baseline	Change score	<i>n</i>	NPI baseline	Change score
1	No abnormal sensory features	10	33.8 ± 13.3	8.5 ± 13.4	9	32.8 ± 11.3	4.7 ± 9.4
2	PPT only	10	41.0 ± 14.1	15.3 ± 13.4	6	39.3 ± 9.6	2.8 ± 10.25
3	PPT + CPT	9	42.3 ± 14.4	7.0 ± 15.8	10	42.5 ± 11.7	7.3 ± 8.1
4	CPT only	6	32.6 ± 12.6	10.3 ± 14.2	9	39.6 ± 10.5	2.6 ± 9.0

Participant's psychological features showed some improvement albeit small in both the MPT and SMP intervention groups. It could be argued that these changes could better relate to the reduction in their pain and disability rather than therapist related factors given that the alternative treatment was self-management. The scores for psychological distress approached threshold for the MPT group (scores of 23–24) (Goldberg, 1978) but mild to moderate stress related to the whiplash injury (IES) was still present in both groups (McFarlane, 1988). This suggests that these participants may warrant further investigation or care from a health psychologist, especially when it is considered that the mean length of time since injury was a little over a year. Despite improvements in reported pain and disability and range of movement in both intervention groups, there was little change in TSK scores, although the changes in the SMP group were statistically greater than those in the MPT group.

Not unexpectedly, the profile of this chronic whiplash group presented as a heterogeneous group with variable and sometimes complex patterns of co-existing physical, sensory and psychological impairments, which characterise those with persistent symptoms following whiplash injuries (Sterling et al., 2003a,b,c). In relation to sensory features, 72.5% of subjects presented with sensory changes, which were relatively evenly distributed between combinations of widespread mechanical hyperalgesia, widespread mechanical and cold hyperalgesia, and cold hyperalgesia only. Neither the MPT nor SMG groups, considered collectively, appeared to react adversely to the respective interventions, even though exercise has been shown to increase sensory hypersensitivity in other conditions thought to demonstrate central hyperexcitability such as fibromyalgia (Staud et al., 2005). However, both treatment protocols (MPT and SMP) emphasised non-provocative management. Exercises were low load and focused on motor relearning. Different types of exercise, for example, higher load exercise approaches focussing on strength training might not yield the same results.

This study was not powered to examine the treatment effects within and between the subject sub-groups based sensory features. However, the variable responses observed in the subgroups (Table 4) suggest that this should be an important area for further research and for consideration in the design of future clinical trials. Based only on a small sample in this study, it appears that the subject sub-classification with both widespread mechanical and cold hyperalgesia (PPT + CPT) had least improvement and exited the trial with persisting moderate neck pain and disability. Yet this was not so for the group with widespread mechanical hyperalgesia alone who obtained an acceptable outcome from MPT. We were surprised by the presence of a group with cold hyperalgesia alone without mechanical hyper-

algesia, which is not a usual finding in other pain conditions (Rasmussen et al., 2004). The baseline scores and outcomes of this subgroup more closely mirrored those of the no sensory subgroup. The isolated sensory alteration of cold hyperalgesia found in this group may merely reflect individual differences in pain perception (Liem et al., 2005) as opposed to representing disturbances in nociceptive processing or could be a product of the low sample size in the subgroups.

This study has shown that physical rehabilitation can produce clinically meaningful changes for patients with chronic whiplash associated disorders in at least the immediate post-treatment period. The effect in the long-term must now be examined. Nevertheless it is suggested that more knowledge needs to be gained about the impact of abnormal sensory features on the effectiveness of physical therapies before such a trial proceeds. The preliminary post-hoc observations in this study suggest that the presence of both widespread mechanical and cold hyperalgesia, indicative of a notable pain syndrome, may indicate a poor response to physical therapies applied as the sole therapy. It is possible that subclassifying patients with chronic whiplash associated disorders, rather than regarding them as a homogeneous group, may assist in gaining a better design for future clinical trials and more definitive information about treatment effects to guide decisions of management in respect to the prescription of physical therapies.

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